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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,675	03/23/2001	James R. Matson	067062.0110	5775

7590 09/20/2002  
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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

AS-7

<b>Office Action Summary</b>	Application No. <b>09/815,675</b>	Applicant(s) <b>Matson</b>	
	Examiner <b>John Kim</b>	Art Unit <b>1723</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Mar 23, 2001
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar 23, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>5-6</u> | 6) <input type="checkbox"/> Other:  |

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 and 8 are indefinite for failing to particularly point out the unit for "100". Claim 5 is indefinite for failing to particularly point out to what does one therapeutic agent is provided.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 © of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-3, 5-6 and 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,287,516 (Matson et al). Matson et al teach a hemofiltration method and system

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comprising a 100 kilo dalton to 150 kilo dalton hemofilter (102) to remove selective inflammatory mediators including TNF, IL-1 beta from blood and connected to an adsorptive device (108) having adsorbents including biological agent including anti-TNF antibody to remove inflammatory mediators (see figure 1; col. 5, line 17-23; col. 11, line 7 - col. 13, line 34).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al as applied to claims 1 and 5 above, and further in view of U.S. Patent No. 6,008,199 (Grinnell et al '199). Claims 4, 7 and 10 essentially differ from the hemofiltration system and method of Matson et al in reciting the provision of one pharmaceutical agent including activated protein C. Grinnell et al '199 teach that activated protein C is used to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system and method of Matson et al to provide one pharmaceutical agent including activated protein C to more effectively treat sepsis caused by inflammatory mediators as suggested by Grinnell et al '199.

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7. Claims 1, 2, 4-5, 7-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,681 (Davidner et al) in view of Grinnell et al '199. Davidner et al teach a hemofiltration method and system comprising a hemofilter (106) to remove selective inflammatory mediators including TNF, IL-1 beta from blood and connected to filter devices (111, 112) to remove inflammatory mediators including endotoxins (see col. 3, lines 8-36; col. 4, line 66 - col. 5, line 62; col. 7, lines 8-30). Davidner et al further teach that his hemofilter removes the inflammatory mediators including TNF, IL-1 beta that are removed by hemofilter of 100 kD - 150 kD of U.S. Patent No. 5,571,418 (Lee et al). Claims 1-2, 4-5, 7-8 and 10 essentially differ from the hemofiltration system and method of Davidner et al in reciting the provision of one pharmaceutical agent including activated protein C. Grinnell et al '199 teach that activated protein C is used to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system and method of Matson et al to provide one pharmaceutical agent including activated protein C to more effectively treat sepsis caused by inflammatory mediators as suggested by Grinnell et al '199.

8. Claims 3, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidner et al in view of Grinnell et al '199 as applied to claims 1 and 5 above, and further in view of U.S. Patent No. 5,523,096 (Okarma et al). Claims 3, 6 and 9 essentially differ from the hemofiltration system and method of Davidner et al in view of Grinnell et al '199 in reciting the

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provision of biological agent to reduce adverse inflammatory mediator effects and adsorptive device associated with hemofilter. Okarma et al teach an adsorptive device comprising human serum albumin on a silica for removing inflammatory mediators including cytokins, IL-1 (see col. 5, lines 10- 40). It would have been obvious to a person of ordinary skill in the art to substitute the adsorptive device including human serum albumin for the filter devices of Davidner et al for removing inflammatory mediators from blood wherein above devices have equivalent function in removing inflammatory mediators.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

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A handwritten signature in black ink, appearing to read "John Kim".

**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
September 18, 2002